FLAWLESS PEN USER GUIDE
BY

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FLAWLESS PEN

USER MANUAL

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FLAWLESS PEN USER MANUAL

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Flawless Pen – Features and Benefits

- Cordless device
- No cross infection - disposable needles
- Variable Speed
- Shorter treatment times
- Adjustable needles depth
- Less pain
- Light weight hand_piece
- Easy to use
- Lower price of consumables
- No side effects
- Easy to transport

Treatment	Improves Skin Texture	Improves Appearance of Scars	Temporary Increase in Skin Permeability	Risk of Hyperpigmentation
Flawless Pen	YES	YES	YES	NONE
Chemical Peels	YES	Some	No	Medium
Micro - dermabrasion	YES	No	No	Low
Fractional Laser	YES	YES	YES	High

Flawless Pen - Application and effects:

- Skin tightening, lifting and rejuvenation
- Acne scars and wound healing
- Improves wrinkles and fine lines
- Minimises pore size
- Improves Alopecia
- Improves stretch marks

What is Medical Needling?

Medical needling is aimed at stimulating the body's own collagen production to reduce the appearance of fine lines and wrinkles, stretch marks, skin laxity and scarring and even cases of hair loss.

The Flawless Pen

The Flawless Pen skin needling system allows for controlled induction of the skin's self repair mechanism by creating micro "injuries" in the skin which triggers new collagen synthesis yet does not pose the risk of permanent scarring. The result is smoother, firmer and younger looking skin.

Skin needling procedures are performed in a safe and precise manner with the use of the sterile Flawless Pen needle head.

The procedure is normally completed within 30 - 60 minutes depending on the required treatment and anatomical site.

The Flawless Pen disposable micro_needling tip comes in sterilised individual packages that are easily replaced and loaded into the device.

The tip has twelve (12) stainless steel micro_needles (32 _gauge) which can be adjusted from 0.25 to 2.75 mm, giving physicians and aestheticians an innovative skin therapy system that is designed to cater to individual patient needs.

The Flawless Pen's needle depth can be adjusted during the course of the procedure to accommodate different treatment areas, and can easily manoeuvre around facial contours and delicate features, such as the eyes, nose and mouth.

The Flawless Pen offers many advantages over other light based and heat based devices; medical needling increases the effectiveness of the treatment while causing less epidermal damage sometimes caused by excess heat and light based therapies, exceptional results, is cost effective, easy to use and has better precision and control than more expensive treatments.

This ground_breaking technology, combined with low cost disposable tips, makes the Flawless Pen a revolutionary breakthrough for beautiful skin.

Practitioner Notes

Flawless Pen Treatment Record

Practitioner Name and Designation

_____

Client Consent Y/N

Photos Taken Y/N

Anaesthetic Type _____

Cleanser Used _____

Needling Serum _____

Always Use Lowest Depth possible

Needle Size 0.25 - 0.5 - 0.75 - 1 (Maximum For Non Medical Practitioners)

1.25 - 1.5 - 2

Body Areas Only - 2.5 - 2.75

Record Depth Number of Passes

Area -

Area-

Area -

Area -

Area -

Post Treatment Products/Serum Applied

Comments

THE PRACTITIONER MUST COMPLETE A FULL MEDICAL HISTORY CONSULTATION AND INFORMED CONSENT BEFORE TREATMENT.

Contraindications:

- Pregnancy and Breastfeeding
- Keloid scars
- History of eczema
- Psoriasis and other chronic conditions
- History of actinic (solar) keratosis
- History of Herpes Simplex infections (see precautions)
- History of diabetes; presence of raised moles, warts on targeted area

Absolute contraindications include:

- **Vascular diseases or cardiac abnormalities**
- **Blood clotting problems, active bacterial or fungal infection,**
- **Immuno- suppression**

Precautions:

Discontinue Retinol/Vitamin A 7 days before using the pen
Do not to treat active acne, rosacea or other inflamed condition
Do not treat open wounds
Patients with a history of cold sores, medication must be used before and after treatment.

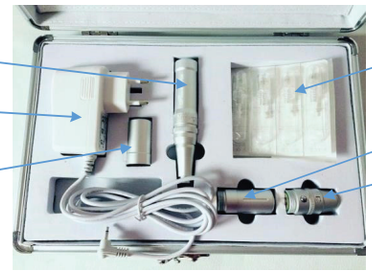
Medical Needling treatments not to be administered for 12 months after Accutane regimen.

Side Effects:

After the procedure, the skin will be red and flushed in appearance in a similar way to moderate sunburn. You may also experience skin tightness and mild sensitivity to touch on the area being treated. This will diminish greatly after a few hours following treatments and within the next 24 hours the skin will be completely healed. After 3 days most visible erythema will be resolved there may also be a mild peeling.

Pen Preparation

What's in the Box?



1. For Cordless use - Always make sure your Flawless Pen has a full charge before starting treatment.
2. Do not over_tighten the Pen Driver.
3. Always make sure the needle depth is set to '0' before inserting a new tip.
4. Always make sure the needle depth is set to '0' before starting a new treatment.
5. Always power Flawless Pen on BEFORE selecting needle depth
6. Always perform 'test patch' on patient before continuing treatment at selected depth
7. Always lift Flawless Pen before changing directions during treatment. Do not turn or pivot while in contact with the skin. Lifting before changing direction will prevent scratching.

- Sunburn
- Tattoos
- Telangiectasia/erythema
- Uncontrolled diabetes
- Vascular lesions

ACKNOWLEDGEMENT and CONSENT

My signature below acknowledges that I have read and understand the content of this informed consent. I have been given ample opportunity to ask questions, all of which have been answered in a satisfactory manner. I understand that results can vary and that no guarantee, neither expressed nor implied, has been or will be, given to me regarding my results. I'm aware of the risks and benefits associated with the Flawless Pen™ Dermal Needling procedure, as well as available alternative treatments. I understand that Dermal Needling is an elective procedure, performed solely for cosmetic purposes, and is not critical to my health. On my own free will, I am requesting and providing my informed consent, to undergo Flawless Pen Dermal Needling treatment(s) at Flawless Aesthetics and Beauty. I assume all risks as my own, I hereby release them from any liability, both seen and unforeseen.

_____ _____ _____

Patient Signature | Name (Printed) | Date

_____ _____ _____

Practitioner Signature | Name (Printed) | Date

PAIN- There may be a very slight burning, scratchy, and irritated sensation to the skin. This is usually temporary and is gone within a few hours after treatment. A sudden reappearance of redness or pain is a sign of infection and you should notify our office immediately.

PERSISTENT REDNESS, ITCHING, AND/OR SWELLING- Itching, redness, and swelling are normal parts of the healing process. These symptoms rarely persists longer than 24 hours with dermal needling. However, treatments received less than 4 weeks apart may induce prolonged symptoms.

ALLERGIC REACTION- Dermal Needling is performed with a head containing 9/12 sterile hypodermic needles, making an allergic reaction nearly impossible; However, a variety of products may be used on the face in conjunction with the Dermal Needling procedure, to which an allergy can occur. Additionally, since Dermal Needling increases the penetration of topical substances, it can cause you to be hypersensitive to products used on the face. If an allergic reaction were to occur, you must contact your practitioner immediately, as it may require further treatment.

LACK OF PERMANENT RESULT- Dermal Needling will not completely or permanently improve skin texture, tone, elasticity, hyper pigmentation, scars, or minimise fine lines and wrinkles. It is important that your expectations be realistic and understand the procedure has its limitations.
Additional procedures may be necessary to achieve desired effect.

UNSATISFACTORY RESULT- Although rare from Dermal Needling, there is a possibility of a poor result from any cosmetic procedure. Dermal Needling may induce undesirable results, including but not limited to skin sloughing, scarring, permanent pigment, and/or other undesirable skin changes. You may be disappointed with the final results of Dermal Needling.

CONTRAINDICATIONS TO DERMAL NEEDLING

Although it is impossible to list every potential risk and complication, the following are recognised as known contraindications to Dermal Needling. Furthermore, it is your responsibility to fully and accurately disclose all medical history prior to initial treatment, as well as provide any necessary updates at all future treatment sessions. If you have any of the conditions listed below, you should bring it to the attention of your practitioner PRIOR to signing this consent form.

- Active acne
- Active infection of any type (bacterial, viral, or fungal)
- Blood thinning medications
- Cardiac disease/abnormalities
- Chemotherapy or radiation
- Collagen Vascular Disease
- Eczema, Psoriasis, or Dermatitis
- Haemophilia / bleeding disorders
- Hormone Replacement Therapy
- Keloid/hypertrophic scaring
- Pregnancy / Lactation
- Raised lesions (moles, warts, etc.)
- Recent chemical peel procedure
- Recent use of some topical creams
- Scleroderma
- Skin Cancer

Charging Instructions:

1. Connect battery to charging unit

2. A red light on the wall charger indicates that the power button has been depressed and the battery is charging

3. Allow the battery to charge for 75 minutes or until the light turns from red to green, indicating that the battery has been fully charged

Note: If the power button is not depressed upon initial insertion into the charging unit, a green light will be displayed. This does not indicate that the battery is fully charged (green is the default colour). Press the power button on the battery once to begin charging.

1. twist ① and ② into one unity

2. conect to the Adapter with electricity, light is yellow

3. press the on-off button of ①Battery, light turns red, it's on charging now

4. when fully charged, light turns yellow, unplug the Adapter

Pre Treatment Instructions

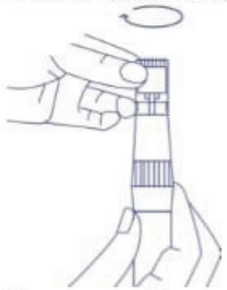
Unseal the product just before treatment and make sure that the device is used in a sterile environment and handled with sterile gloves.

Take out the disposable needle and check needles are in good condition, pull back the spring to ensure a fluid movement.

Inserting and removing the Needle:

To insert needle:

1. Insert needle turning in a clockwise direction
2. Do not squeeze too hard.



To separate needle:

1. Hold the needle tip and turning counter-clockwise till needle comes out
2. Separate needle

DERMAL NEEDLING INFORMED CONSENT

INTRODUCTION TO DERMAL NEEDLING & THE FLAWLESS PEN

The concept of Dermal Needling is based on the skin's natural ability to repair itself when it suffers physical damage such as cuts, burns, abrasions or other injuries. Immediately after an injury to the skin, our body begins the healing process, triggering new collagen synthesis. The Flawless Pen is a Dermal Needling device that intentionally creates very superficial "micro-injuries" to the outermost layer of the skin, inducing the healing process including new collagen production. Dermal Needling has been shown to reduce the visibility of acne scars, fine lines, and wrinkles, diminish hyper pigmentation, and improve skin tone and texture, resulting in smoother, firmer, younger looking skin.

ABOUT THE PROCEDURE

At Flawless Aesthetics and Beauty Dermal Needling is performed using The Flawless Pen. This procedure is performed by a trained professional. The Flawless Pen Dermal Needling procedure is performed in a safe and precise manner with a single-use sterile needle head. The treatment session usually takes about 30-60 minutes, depending on the area(s) being treated. After the procedure, the skin will be red, with mild swelling and/or bruising, and your skin might feel tight and sensitive to the touch. Although these symptoms may take 2-3 days to resolve completely, they will diminish significantly within a few hours after treatment.

ALTERNATIVE TREATMENTS

Alternative treatments to Dermal Needling may include the use of routine skin care, oral and/or topical prescription and/or non-prescription medications, microdermabrasion, laser treatments, and even cosmetic/plastic surgery. Each of these alternatives carry their own inherent risks and benefits. However, since this treatment is elective and is done for cosmetic purpose only, no treatment at all should also be considered a viable alternative.

RISKS OF NEEDLING

Although the majority of patients do not experience any complications with Dermal Needling, it is important you understand that risks do exist. The Dermal Needling procedure is minimally invasive, utilising a set of micro-needles to inflict multiple, tiny, puncture/lacerations to the outer layer of the skin. Because Dermal Needling penetrates the skin, it inherently carries health risks, including but not limited to those listed below. You should discuss any and all health concerns with your practitioner or attending healthcare provider **PRIOR** to signing this consent form.

INFECTION- Infection is very unusual. However, viral, bacterial, and fungal infections can occur anytime the integrity of the skin is compromised. Should infection occur, you must contact or return to our office immediately, as additional treatment will likely be necessary

PIGMENT/COLOUR CHANGE- Because dermal penetration is so superficial it doesn't extend into the layer of the skin containing melanocytes, hyper pigmentation is very rare with Dermal Needling;
However, failure to follow post treatment instructions can put you at risk for hyperpigmentation. You **MUST** avoid sun exposure for a 1 to 2 weeks after a Dermal Needling treatment. You should also wear a daily SPF over over 30, which your practitioner can recommend. Lastly, avoid picking and/or peeling the skin during healing period.

SCARRING- Although normal healing after the procedure is expected, abnormal scars may occur in both the skin and deeper tissues. In rare cases, thickened or keloid scars may result, especially if you are prone to keloid scarring anyway. Scars may be unattractive and of different colour than surrounding skin. Additional treatments may be needed to treat scarring.

Medical History

Questions	Yes	No	Comments
Have you any Allergies?			
Do you take any prescribed medication?			
Do you take any over the counter Medication including supplements?			
Are you pregnant, planning to be or breastfeeding?			
Please provide details of any recent surgery?			
Have you any history of Skin Cancer?			
Have you previously received any Wrinkle relaxation treatment or dermal fillers? If so when?			
Do you have any heart or vascular conditions?			
Do you suffer fainting or high/low blood pressure?			
Are you Diabetic?			
Are you sensitive to the Sun?			
Have you any needling, chemical peels, IPL or Laser Treatment in the last month?			
Do you suffer from an Auto Immune Disease?			
Do you suffer from any skin conditions, Acne, Eczema, Dermatitis, Psoriasis?			
Do you have any Keloid Scars?			
Do you suffer from Herpes Simplex?			
Do you use retinol Products on the Skin?			
Do you have any clotting or bleeding disorders?			
Do you have any other medical or skin conditions not listed above?			

If the answer to any of the above is yes your practitioner may decide you are not suitable for this treatment.

I confirm that I have answered the above questions honestly and to the best of my knowledge and that my practitioner has explained the procedure to me in detail.

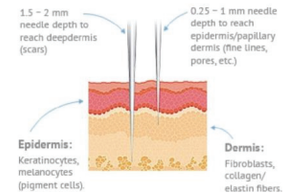
Signed _____ Print _____ Date _____

Treatment Instructions

1. Apply a topical anaesthetic leave for recommended time.
2. Clean skin by removing all make up, moisturiser, self.tanner, sunscreen and numbing cream etc. with Flawless Cleanser, or mild soap and water.
3. Section off and Mark smaller areas out if covering a large area.
4. Apply lubricating topical such as Flawless Hyaluronic Acid to treatment area.
5. Activate the Flawless Pen by pressing the power button.

6. Select needle depth according to approximate thickness of skin and indication *(refer to Fig 1 and Fig 2 as a guide only - for best practice always start at a lower depth first)*

Fig 1


1.5 – 2 mm needle depth to reach deepdermis (scars)
0.25 – 1 mm needle depth to reach epidermis/papillary dermis (fine lines, pores, etc.)
Epidermis:
Keratinocytes, melanocytes (pigment cells).
Dermis:
Fibroblasts, collagen/ elastin fibers.

7. Begin treatment by simultaneously making contact with the skin and gliding in a 90 degree made across the area at a rate of 1 inch per second (10 pence piece).

   Continue until a single pass has covered the whole area.

8. Observe the effect on the skin and adjust needle depth accordingly (*see Fig 1 and 2*).*
9. Repeat process with a pass across the treatment area if necessary (MAX 5).

Fig 2

Indication / Needle Size	0.2 mm	0.25 mm	0.5 mm	0.75 mm	1.0 mm	1.5 mm	2.0 mm	2.5 mm
Hair Regeneration, Regrowth	√	√	√					
Fine Lines		√	√					
Anti Aging, Anti Wrinkle			√	√	√			
Open Pores			√	√	√			
Pigmentation Marks			√	√	√			
Acne Scars			√	√	√			
Light Scars			√	√	√			
Cellulite					√	√	√	
Stretch Marks					√	√	√	√
Deep Scars						√	√	√

**For proper regulatory compliance, non physician use of this device should be limited to an erythematous effect only and not more than 1mm. The treatment endpoint should be mild to moderate erythema. Flawless Pen is a Class I FDA registered device MHRA (Pending).*

Post Treatment Instructions

Immediately

Step 1: Using a damp gentle gauze or disposable cloth, pat down the treated area.
Step 2: Reapply thin layer of Flawless Hyaluronic Acid or Hydrating serum.
Step 3: Apply Flawless Vitamin C and E Serum and or Retinol cream at night.
Step 4: Apply Sunscreen of at least SPF30. Day

Days 2 & 3: As above

1. Cleanse – clean Skin using Flawless Aesthetics and Beauty Clarifying Cleanser.
2. Revive – apply Power Peptide Restorative Serum over entire treatment area
3. Sooth – apply Vitamin C and E 2 in one Serum.
4. Protect – apply protective, BROAD SPECTRUM Sunscreen OF AT LEAST SPF 30. Repeat as necessary throughout the day Note: Avoid sweaty exercise and and sun exposure during first 12 hours.

Day 4: Resume Normal Skin Care Routine

Single Treatment Protocol*:	**Multi-treatment Protocol:**
Fine lines	*(Series of 3-6 Tx at 6-8 week intervals)*
Texture	Moderate to Deep Wrinkle
Large Pore Size	Atrophic Acne Scars
Uneven Skin Tone	Striae/Stretch Marks
Minor Blemishes	Traumatic Scars
	Non-Keloid Hyper-trophic Scars

***Protocols apply to all skin types**

Cleaning and Storage

1. Always dispose of single- use needle tip in sharps container IMMEDIATELY after each treatment.

2. DO NOT keep or store disposable tips for later use.

3. Using a clean gauze or paper towel, wipe down the entire surface area with Isopropyl Alcohol before and after treatment. Use Alcohol soaked cotton swab to clean in tight spaces.

4. Always wipe with alcohol before returning the Flawless Pen to its storage case for safe keeping.

Store away from children and in a safe, clean, dry, place

Remember: The Flawless Pen is an intricate instrument and your valuable tool

Warranty:

1. This product is manufactured under strict quality control and inspection processes.
2. The Practitioner/Business owner is responsible for getting electrical devices tested as per health and safety law.
3. Warranty is to cover the operating defaults after the purchase during the warranty period (12 months after the purchase)
3. When this product goes out of order under the normal use of a customer, we will repair or replace it during the warranty period.
4. The damages (defaults) prescribed below are **NOT** to be covered by warranty.

• Users faults by lack of care or water damage
• Unauthorised electric currency connection defaults
• Faults by the users own intention or unauthorised repairs
• Damages caused by natural disaster. (Fire, Flood, Earthquake, lightning etc) •

Replacement of parts excluding disposable needles